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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,043	02/13/2004	Eliezer Rapaport	21095-00008-US1	3919

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EXAMINER

ANDERSON, JAMES D

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 04/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/777,043	<b>Applicant(s)</b> RAPAPORT, ELIEZER	
	<b>Examiner</b> James D. Anderson	<b>Art Unit</b> 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☒ Claim(s) 2 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>3/11/04, 5/12/05</u> | 6) <input type="checkbox"/> Other: ____.  |

## **DETAILED ACTION**

### ***Formal Matters***

1. Claims 1-11 are pending and are the subject of this Office Action.

### ***Election/Restriction***

2. This application contains inventions or groups of inventions that have been determined to form a single general inventive concept under PCT Rule 13.1. Therefore, Claims 1-11 are the subject of this Office Action.

### ***Priority***

3. The instant application is a continuation of co-pending U.S. Patent Application 10/111,167, filed April 22, 2002, (now U.S. Patent No. 6,723,737; issued April 20, 2004) which was a U.S. national stage filing of PCT/US00/28769 filed October 18, 2000 and designated the U.S., which in turn claimed priority from U.S. Provisional Patent Application S.N. 60/160,634 filed October 20, 1999.

### ***Specification Objections***

4. The disclosure is objected to because of the following informalities: the word "weigh" is misspelled (Page 1, Line 36). The correct spelling is ---weight--- as found elsewhere in the Specification. Appropriate correction is required.

### ***Claim Objections***

5. Claim 2 objected to because of the following informalities: the word "monphosphate" is misspelled. The correct spelling is ---monophosphate--- as found elsewhere in the claims (see especially Claim 1). Appropriate correction is required.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

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be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1-11 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 1-20 of U.S. Patent No. 6,723,737. Although the conflicting claims are not identical, they are not patentably distinct from each other. The subject matter claimed in the instant application is claimed in the patent. Both the instant application and the patent are drawn to methods of treating overweight/obesity by administering adenosine 5'-triphosphate. The patent discloses the same amounts and routes of administration of adenosine 5'-triphosphate as the instant application. The only difference between the instant application and the issued patent is that the claims in the instant application include in the composition the addition of an antagonist of adenosine A1 receptor (e.g. caffeine or theophylline) in addition to adenosine 5'-triphosphate.

***Claim Rejections - 35 USC § 112, Second Paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-3 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1-3 recite the limitation “and at least one member selected from the group consisting of adenosine 5'-triphosphate and adenosine 5'-monophosphate” in Lines 2-3. There is insufficient antecedent basis for this limitation in the claims. “And at least one member” implies that the composition can be comprised of a combination of adenosine 5'-triphosphate and adenosine 5'-monophosphate. It is unclear in what ratio and/or how much of each compound is to be present in the mixtures. Thus, the instant claims do not distinctly claim the subject matter the applicant regards as his invention.

***Claim Rejections - 35 USC § 112, First Paragraph - Enablement***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-11 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of obtaining or maintaining weight loss (Claims 1-2), does not reasonably provide enablement for the prevention of weight gain

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nor for the use of AMP (Claims 3-11). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApl 1986) at 547 the court recited eight factors:

- 1) The quantity of experimentation necessary,
- 2) The amount of direction or guidance provided,
- 3) The presence or absence of working examples,
- 4) The nature of the invention,
- 5) The state of the prior art,
- 6) The relative skill of those in the art,
- 7) The predictability of the art, and
- 8) The breadth of the claims.

The instant specification fails to provide guidance that would allow the skilled artisan to practice the instant invention without resorting to undue experimentation, as discussed in the subsections set forth below:

1. The quantity of experimentation necessary

The skilled artisan would expect the etiology of obesity to be complex and be caused by the interactions of multiple biological pathways and therefore, highly unpredictable, absent a clear understanding of the structural and biochemical basis for

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the absolute prevention of weight gain. The instant specification sets forth no such understanding or any criteria for extrapolating beyond those methods actually demonstrated.

The burden of enabling the prevention of weight gain (i.e. the need for additional testing) would be greater than that of enabling a treatment for weight gain in a human. In the instant case, the specification does not provide guidance as to how one skilled in the art would go about the absolute prevention of weight gain or a human could be kept from gaining weight. Nor is there any guidance provided as to a specific protocol to be utilized in order to prove the efficacy or the presently claimed method of preventing weight gain in a human. Specifically, it is highly unlikely, and the Office would require experimental evidence to a claim such as that of Claim 3, which claims to prevent weight gain by the simple administration of ATP and caffeine, for example.

## 2. The amount of direction or guidance provided

The specification provides no direction for ascertaining how to absolutely prevent any and all weight gains from occurring and the applicant has not demonstrated that the method of using ATP and caffeine, for example, can reasonably be expected, *a priori*, to exhibit the requisite prevention of weight gain. Further, Applicant has provided no guidance on how AMP can be used in the methods recited in the instant claims.

## 3. Presence or absence of working samples

Only a limited selection of specified methods for administering ATP are enumerated by the specification, and the working examples are even more limited and although the applicant has demonstrated the use of ATP for overweight human



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volunteers, they have not provided any working examples demonstrating the absolute prevention of weight gain, indefinitely (indeed, one could not be provided).

4. The nature of the invention

The claimed invention relates to the absolute prevention of weight gain.

5. State of the prior art

*Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults*, NIH Publication No. 98-4083, September, 1998 represents a standard publication in the art and as such is directed to those having skill in the art.

6. Relative skill of those in the art

The relative skill of those in the art is generally that of a Ph.D. or M.D.

7. Predictability of the art

*Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults* demonstrates the unpredictability of the claimed subject matter.

In the instant case, Claims 1-6 recite the limitation "adenosine 5'-monophosphate" however this particular compound is not disclosed anywhere in the Specification. The Specification provides a written description and examples of the use of adenosine 5'-triphosphate in methods for obtaining weight loss in humans but does not disclose the use of adenosine 5'-monophosphate for the same. Therefore, while there are working examples relevant to the use of adenosine 5'-triphosphate in the desensitization of adenosine receptors and its use as a potential treatment for obtaining weight loss in humans, no working examples or description regarding the use of adenosine 5'-monophosphate for these purposes are present in the disclosure. The

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nature of the invention is complex, being directed to biological and physiological processes and the manipulation of those processes in obtaining weight loss in humans. The state of the prior art is silent with respect to whether or not adenosine 5'-monophosphate will have the same effect as adenosine 5'-triphosphate in eliciting weight loss in humans. Whether or not a particular biological molecule will have an effect on weight loss in humans is unpredictable, in that it requires empirical screening. In view of all of these factors and the lack of description in the disclosure regarding the use of adenosine 5'-monophosphate in a composition for eliciting weight loss in humans, undue experimentation would be required of the skilled artisan to practice the claimed invention.

Given the above, it is clear that the art to which the instant invention relates involves a relatively high degree of unpredictability.

#### 8. Breadth of the Claim

Claim 3 is inclusive of the prevention of any and all weight gain.

Thus, the specification fails to enable one of ordinary skill in the art to practice and use the methods of Claims 1-11.

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**Conclusion**

9. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James D. Anderson whose telephone number is 571-272-9038. The examiner can normally be reached on MON-FRI 9:00 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
James D. Anderson  
Examiner  
Art Unit 1614

JDA

  
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